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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 522

Implantation or Injectable Dosage Form New Animal Drugs; Hyaluronate Sodium

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Anika Therapeutics, Inc. The supplemental NADA provides for equine use of hyaluronate sodium injection containing 11 milligrams hyaluronate sodium per milliliter (mg/mL) rather than the currently approved 10 mg/mL.

EFFECTIVE DATE: (*Insert date of publication in the* **Federal Register.)**

FOR FURTHER INFORMATION CONTACT: Dennis M. Bensley, Jr., Center For Veterinary Medicine (HFV–143), Food and Drug Administration, 7500 Standish Pi., Rockville, MD 20855,301-594-4105.

SUPPLEMENTARY INFORMATION: Anika Therapeutics, Inc., 236 West Cummings Park, Woburn, MA 01810, formerly Anika Research, Inc., 160 New Boston St., Woburn, MA 01801, filed supplemental NADA 122–578 that provides for equine use of a 11 -mg/mL Hyvisc (hyaluronate sodium) injection instead of the currently approved 10-mg/mL injection. The injection is for intra-articular use in horses for treatment of joint dysfunction due to noninfectious synovitis associated with equine osteoarthritis. The drug is limited to use by or on the order of a licensed veterinarian. The supplemental NADA is approved as of September 30, 1998, and 21 CFR 522.1145 is amended in paragraph (a)(2) and by adding paragraph (f) to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514,11 (e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this supplemental application may be seen in the Dockets Management Branch (HFA–**305),** Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

In addition, the sponsor has changed its name and address. The regulations are amended in 21 CFR 51 O.6OO(C) to reflect the changes in sponsor name and address.

FDA has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects

21 *CFR Part 510*

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegate to the Center for Veterinary Medicine, 21 CFR parts 510 and 522 are amended as follows:

PART 510-NEW ANIMAL DRUGS

1. The authority citation for21 CFR part510 continues to read as follows:

Authority: 21 U.S.C. 321,331,351, 352,353, 360b, 371, 379e.

§ 510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications is* amended in the table in paragraph (c)(1) in the entry ‘ ‘Anika Research, Inc. ” and in paragraph (c)(2) in the entry “060865” by removing the sponsor name and address and inserting in its place ‘ ‘Anika Therapeutics Inc., 236 West Cummings Park, Woburn, MA 01801”.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

4. Section 522.1145 is amended by revising paragraph (a)(2) and adding paragraph (f) to read as follows:

§ 522.1145 Hyaluronate sodium injection.

(a) * * *

(2) *Sponsor. See* 000009 in § 51 O.6OO(C),

* * * * *

(f)(l) *Specifications.* Each milliliter of sterile aqueous solution contains 11 milligrams of hyaluronate sodium,

(2) *Sponsor. See 060865* in § 51 O.6OO(C).

(3) *Conditions of* use-(i) *Amount.* Small and medium-size joints (carpal, fetlock)—22 milligrams; larger joint (hock)—44 milligrams.

(ii) *Indications for use.* Treatment of joint dysfunction in horses due to noninfectious synovitis associated with equine osteoarthritis.

(iii) Limitations, For intra-articular injection in horses only. Treatment may be repeated at weekly intervals for a total of three treatments. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: October 25, 1998

October 25, 1998

Margaret Ann Miller

Margaret Ann Miller
Acting Director
Office of New Animal Drug
Evaluation
Center for Veterinary
Medicine

[FR Dec. 98-???? Filed ??-??-98; 8:45 am]

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